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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,270	09/24/2001	Gerd Geisslinger	016915-0244	2372

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EXAMINER

BAHAR, MOJDEH

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 05/07/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/914,270	GEISSLINGER ET AL.
	Examiner Mojdeh Bahar	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 11-19 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 11-19 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. 
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> .	6) <input type="checkbox"/> Other: _____

### **DETAILED ACTION**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-19 provide for the use of arylpropionic acid in making medicaments, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 11-19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

In order to expedite prosecution, claims 11-19 are treated as “method of making” claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 13,16 and 19 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bang et al. (WO 98/47502).

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Bang et al. (WO 98/47502) teaches preparing medicaments containing R-ibuprofin, known inhibitors of NF-KB useful in treating chronic and acute pain, inflammation, tumors, and autoimmune diseases, see abstract and claims 1-4, and example 2 on page 5 in particular.

Claims 11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Geisslinger et al. (USPN 5,200,198).

Geisslinger et al. (USPN 5,200,198) discloses a gelatin capsule effective in treating diseases characterized by pain or inflammation comprising 75 or 100 mg. of 99.5% pure R-flubiprofen, pharmaceutical adjuvants and carriers, see col. 7 line 54 to col. 8 line 3. Geisslinger et al. further teaches the particular salts recited herein, i.e., salts of alkali metals, alkaline earth metals, ammonium and amino acid salts, in particular lysinate, see claims 1-9 in particular. Geisslinger et al. finally teaches that the medicament comprises retarding additives, see claim 10 for example.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisslinger et al. (USPN 5,200,198).

Geisslinger et al. (USPN 5,200,198) discloses a gelatin capsule effective in treating diseases characterized by pain or inflammation comprising 75 or 100 mg. of 99.5% pure R-flubiprofen, pharmaceutical adjuvants and carriers, see col. 7 line 54 to col. 8 line 3. Geisslinger et al. further teaches the particular salts recited herein, i.e., salts of alkali metals, alkaline earth metals, ammonium and amino acid salts, in particular lysinate, see claims 1-9 in particular. Geisslinger et al. finally teaches that the medicament comprises retarding additives, see claim 10 for example. Geisslinger et al. also teaches a medicament comprising from about 95%:5% to about 60%:40% of R-flubiprofen: S-flubiprofen. Geisslinger et al. also teaches that each unit dosage form can contain from 10 to 100 mg of the enantiomer mixture, see cols. 7-8 and claim 3 in particular.

Geisslinger et al. does not particularly teach the weight in milligram of each of the enantiomers.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ R-flubiprofen and S-flubiprofen in the weight ranges herein in a mixture.

One of ordinary skill in the art would have been motivated to employ R-flubiprofen and S-flubiprofen in the weight ranges herein in a mixture because the weight percentages as well as the total weight of both enantiomers is taught by Geisslinger.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The

examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar  
Patent Examiner  
April 29, 2003

  
SREENI PADMANABHAN  
PRIMARY EXAMINER

5/4/03